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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,706	09/11/2003	Simon L. McGurk	029318-0968	4753
31049 7590 05/01/2009 Elan Drug Delivery, Inc. c/o Foley & Lardner 3000 K Street, N.W. Suite 500 Washington, DC 20007-5109				
EXAMINER				
SILVERMAN, ERIC E				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
05/01/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/659,706

**Applicant(s)**

MCGURK ET AL.

**Examiner**

ERIC E. SILVERMAN

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-12 and 14-47 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 23, 29 and 44-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 12, 14-22, 24-28, 30-43 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed 4/15/2009 was received. Claims 1-5, 7-12, and 14-47 are pending, claims 9-11, 23, 29, and 44-46 are withdrawn, and claims 1-5, 7, 8, 12, 14-22, 24-28, 30-43 and 47 are treated on the merits in this action.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7, 8, 12, 14-22, 24-28, 30-43 and 47 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The independent claims now require water from "greater than 30% to about 92%" by weight. The original disclosure does not support this recitation. The original disclosure only supports "about 30% to about 92%" by weight. There is no support for the amended claims, which exclude 30% from the range. Claim 4 is not included in this rejection, because it limits the range of claim 1 to a range that is supported by the original disclosure.

Claims 1-5, 7, 8, 12, 14-22, 24-28, 30-43 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims are not enabled when the artisan cannot make or use the invention without undue experimentation. In this case, the artisan would not be able to use the invention without undue experimentation.

Undue experimentation is considered in view of the factors enumerated in MPEP 2164.04(a). All of these factors have been considered, and the most relevant are discussed below.

1. *Breadth of the claims/Nature of the invention*

The claims read on a homogeneous gelatin composition, which incorporates particles of active agent. The particles have surfactant adsorbed to their surface. Water is present in more than 30% by weight of the composition. The only disclosed use of these compositions is delivering active agents (which may include diagnostic agents) to a subject.

2. *State of the prior art*

Delivery systems having active drug particles with surfactants adsorbed to their surface dispersed homogeneously in gelatin are known. See US. 4,882,157 to Yang. In such compositions, the maximum amount of water is 30%. Yang explains that if there is more than 30% water, the compositions are inoperable because of microorganism growth. Yang at 6:60-68. Thus, when the amount of water is more than 30%, such compositions are taught not to be useful for delivering active agents.

3. *Level of predictability in the art*

With regard to the disclosed use, the art is strongly counter-predictive. The art indicates that an artisan would expect microorganism growth to be such a problem when water contents are above 30% that the dosage form is inoperable.

4. *The amount of direction provided by the inventor and the working examples*

Nothing in the original disclosure teaches the artisan how to overcome the microorganism problem discussed in Yang. The inventor does not appear to recognize this problem.

5. *The quantity of experimentation required to use the invention*

In order to use the invention, the artisan would have to solve the significant problem of eliminating microorganism growth to make the dosage form useful. The artisan would have to start from scratch, as the inventor does not address this problem. The artisan would not expect to succeed, because neither the prior art nor the inventor offer any solutions to this problem.

Because the art teaches that there are significant problems with the operability of the instant invention which neither the art nor the inventor address, the artisan would require undue experimentation in order to use the claimed invention.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/  
Examiner, Art Unit 1618